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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,330	06/23/2003	Clarence Nathaniel Ahlem	202.2D2	9052

26551 7590 05/18/2007

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,330	AHLEM ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28 and 119-146* is/are pending in the application.

4a) Of the above claim(s) *25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119-146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/21/2007 and 3/20/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 25-28 and 119-146 are pending in the present application. Claims 25-28 stand withdrawn from further consideration as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

3. The rejection of claims 80-86, 88, 90-111 and 113 -118 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 102

4. Claims 119, 130, 139 and 141 are rejected under 35 U.S.C. 102(b) as being anticipated by Lorie (US 5,461,042 or US 5,387,583).

Lorie teaches the use of androstenediol for enhancing the protective response of the immune system against immune suppressive influences such as radiation, viral infection etc. (see the entire articles, especially '**042**, col. 2, lines 41-49; col. 4, lines 16-35; Examples 1-5 and '**583**, Abstract, col. 3, lines 31-62; Examples 1-5). The references teach various administration routes including subcutaneous (see for

example, **'042**, col. 4, lines 36-68). The method of use taught by the references is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

5. The rejection of claims 80-86, 88, 90-111 and 113-118 under 35 USC 103(a) over Lorie (US 5,461,042) is made moot by the cancellation of the instant claims.

6. Claims 119-146 are rejected under 35 USC 103(a) over Lorie (US 5,461,042 or US 5,387,583) in view of Carr (J. Neuroimmunology, 1998) in combination.

Lorie teaches the use of androstenediol for enhancing the protective response of the immune system against immune suppressive influences such as radiation, viral infection etc. (see the entire articles, especially **'042**, col. 2, lines 41-49; col. 4, lines 16-35; Examples 1-5 and **'583**, Abstract, col. 3, lines 31-62; Examples 1-5). The references teach various administration routes including subcutaneous (see for example, **'042**, col. 4, lines 36-68).

The instant claims differ from the reference by encompassing specific amounts and/or treatment regimens not taught by Lorie. However, Carr teaches the immunomodulatory effect of androstenediol and subcutaneous administration of 32-320 mg/kg (see the entire article, especially Abstract and Discussion).

Based on the combined teachings of the cited references the utilization of androstenediol to enhance the immune system or to treat an immune suppressive

condition irrespective of underling cause would have been obvious to the skilled artisan in the art at the time of the invention.

Claims 120-129, 131-138 and 142-146 differ from the above references by reciting specific treatment regimens.

However, (a) the medical art teaches various treatment regimens dependent on patient age, sex, condition etc. (see for example, US 5,489,581, col. 11, lines 10-25, additional references will be provided upon request) and (b) Lorie teaches dosages is dependent on size and condition of the host as well as route of administration, thus, the claimed treatment regimens are prima facie obvious.

Response to Arguments

7. Applicant argues the recited dosages and dosing regimens are outside the teaching of '042. Applicant also argues the fact that the invention may have been made using routine methods is irrelevant to patentability and the only relevant issue is whether '042 fairly teaches or suggests the claimed subject matter. In addition, in the declaration filed February 21, 2007, applicant argues unexpected results based on neutrophils response. Applicant's argument was considered but not persuasive for the following reasons.

As discussed over in #s 4 and 6, the art teaches androstenediol, in various concentrations, enhances the protective response of the immune system. The art also teaches the production of immune regulators such as cytokines (see '583, Abstract and col. 3, lines 31-44). Based on the teachings of the cited prior art and the level of skill of

the ordinary artisan in the art at the time of the present invention increase in the number or activity of neutrophils would be inherent to the treatment method taught by the prior art.

In response to applicant's argument that the fact that the invention may have been made using routine methods is irrelevant to patentability and the only relevant issue is whether '042 fairly teaches or suggests the claimed subject matter, it is noted that the said routine method(s) is evidence of the level of skill of the ordinary artisan in the art at the time of the present invention. Said level of skill in combination with the teachings of the prior art is relevant to the patentability of the claimed invention.

For these reasons and those given in the previous Office Action, the claimed invention is prima facie obvious.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Barbara P. Badio Ph.D.
Primary Examiner
Art Unit 1617

BB
May 7, 2007